



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,724	09/25/2003	W. Edward Robinson JR.	UCI-12094	8496
<div>23535      7590      08/10/2007 MEDLEN &amp; CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105</div>				
			EXAMINER HUYNH, CARLIC K	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 08/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/672,724

**Applicant(s)**

ROBINSON ET AL.

**Examiner**

Carlic K. Huynh

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks filed on June 8, 2007 is acknowledged.

#### ***Status of the Claims***

1. Claims 28-32 are pending in the application, with claims 31-32 having been withdrawn in response to the restriction requirement submitted on February 23, 2007. Accordingly, claims 28-30 are being examined on the merits herein.

#### ***Response to Arguments***

2. Applicants have argued that "claims 31-32 were improperly withdrawn" in an "Amendment-After Non-Final Rejection" filed on June 8, 2007 because the Examiner cited 37 CFR 1.142(b) which relates to group restriction and not to species election. The arguments were not found persuasive because the Applicants have made an election of species, zidovudine as the reverse transcriptase inhibitor, in a response to the Restriction/Election filed on February 23, 2007. Claims that were drawn to reverse transcriptase inhibitors other than zidovudine were properly withdrawn in order to facilitate prosecution.
3. Applicants have the "μ" from figure 3B in an "Amendment-After Non-Final Rejection" filed on June 8, 2007. Accordingly, in light of the amendments, the objection to the drawings has been withdrawn.
4. Applicants have amended the specification in an "Amendment-After Non-Final Rejection" filed on June 8, 2007 to capitalize trademarks used in the specification. Accordingly, in light of the amendments, the objection to the specification has been withdrawn.

Art Unit: 1617

5. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on June 8, 2007, with respect to "Obviousness Rejection and Priority Information" to claims 28-30 has been fully considered and are persuasive. The priority of the application has been found to be March 27, 1998, not December 21, 2000. Thus, the Rejections under 35 U.S.C. § 103 to claims 28-30 as being unpatentable over (1) De Clercq (Reviews in Medical Virology. Jul/Aug 2000. vol. 10, no. 6, pages 255-277; as cited previously) and (2) Beale et al. (Antiviral Research, June 1, 2000, vol. 46, pages 223-232; as cited previously) have been withdrawn in light of the arguments.
6. Applicant's arguments with respect to claims 28-30 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to claims 28-30 are used herewith.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (The New England Journal of Medicine, 1993, Vol. 328, No. 23, pp. 1686-1695) in view of Robinson et al (Proceedings of the National Academy of Sciences of the United States of America, 1996, Vol. 93, pp. 6326-6331).

Hirsch et al. teach treatment of HIV infection with zidovudine, which is also known as AZT (abstract). Hirsch et al. further teach resistance to zidovudine (page 1688). Hirsch et al.

Art Unit: 1617

also teach using combination therapy because of problems related to drug failure and resistance and agents used in combination therapy target the different stages in the replicative cycle of HIV, including targeting the integration of HIV DNA with integrase inhibitors (page 1691 and Table 1). The combination therapy taught by Hirsch et al. employ the use of zidovudine and a protease inhibitor or zidovudine and another reverse transcriptase inhibitor e.g. didanosine (page 1691).

Hirsch et al. do not teach combination therapy with integrase inhibitors. In fact, Table 1 acknowledges that no integrase inhibitors were discovered at the time of publication (Table 1).

Robinson et al. teach integrase inhibitors and that integrase inhibitors can be used to treat HIV (abstract).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ zidovudine of Hirsch et al. to be used with integrase inhibitors to treat HIV infection because the compounds of Robinson et al. teach integrase inhibitors and according to Hirsch et al. and Robinson et al., zidovudine can be used in a combination therapy and integrase inhibitors can be used in combination therapy for treating HIV infection.

The motivation to combine the compounds of Hirsch et al. to the compounds of Robinson et al. is that the compounds of Robinson et al. can be used in a combination therapy to treat HIV infection.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third

Art Unit: 1617

composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding at least partially resistant and highly resistant as recited in claims 28-29, it is noted that Hirsch et al. teach resistance can develop in long term therapy with zidovudine (page 1688). Since Hirsch et al. teach merely resistance to zidovudine, it is obvious that the degree of resistance to zidovudine is addressed. Thus, Hirsch et al. teaches at least partially resistant and highly resistant as recited in instant claims 28-29.

### ***Conclusion***

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh



**SHENGJUN WANG**  
**PRIMARY EXAMINER**